Active	<b>Siemens Critical C</b>	are Analysers SOP	Version: 2.00
Author: D Harrison	Doc Manager: D Harrison	Authorised by: Kath Ashton	Ver Date: 03/08/09
		Signature:	



# SIEMENS RAPIDLAB 1200 SERIES & RAPIDPOINT 405 CRITICAL CARE ANALYSERS

### STANDARD OPERATING PROCEDURE

**(Version 2.00)** 

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THIS DOCUMENT MUST BE READ BEFORE PERFORMING ANY ANALYSIS OR CARRYING OUT MAINTENANCE PROCEDURES ON THE ANALYSER

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	Related Documents
Hazard Data Sheets	Siemens electrode conditioner solution, Siemens Deproteiniser, Siemens Rapidpoint
	400/405 wash waste cartridge, Siemens Rapidpoint 405 AQC cartridge, Siemens
	Rapidpoint 405 measurement cartridge, Siemens reference electrode fill solution, Na,
	K, Ca, Cl electrode fill solution, pH electrode fill solution, Rapidlab 1200 reagent
	cartridge, Rapidlab 1200 wash cartridge
Risk Assessments	Siemens Rapidpoint 405 Gas Analyser, Siemens Rapidlab 1200 series analysers
Others	Siemens RapidComm SOP, Siemens 405 Critical Care analyser Maintenance Log,
	Siemens 1200 series Critical Care analyser Maintenance Log.
	Siemens critical care analyser list

<u>Significant changes from previous version</u> – Removal of 800 series SOP, change of Name from Bayer to Siemens, Ward 9A analyser re-located to Ward 6B, Analyser list transferred to separate information document. Reported interference to glucose & lactate from Pralidoxime Iodide. Clinical interpretations deleted, contact laboratory for these.

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#### <u>Instrumentation</u> –

Information concerning individual chemistries: - principles of analysis, clinical interpretation etc. are to be found in the appendices at the end of this document.

Parameters available on each instrument vary according to location.

The instruments and locations are listed in the document - 'Siemens critical care analyser list'

#### Reagents and Quality Control -

All reagents and QC are obtained from Siemens Medical Solutions Diagnostics Limited Sir William Siemens Square Frimley Camberley Surrey GU16 8QD Tel: 0845 600 1955 (24hr. service) 0845 600 1966 (orders)

Stocks of all consumables are ordered by Blood Science on behalf of all other Directorates and are held centrally in the laboratory. A small working stock is kept in each location.

IF YOU INSTALL THE LAST CARTRIDGE ON AN INSTRUMENT PLEASE NOTIFY THE BMS WHO WILL NEXT VISIT THE LOCATION TO REPLENISH THE STOCK.

(The BMS next to visit the analyser will be found on the weekly rota)

RECORD THE REAGENT INSTALLATION ON THE APPROPRIATE LOGSHEET.

#### **Quality Control** –

For Rapidpoint 405 & Rapidlab 1200 series analysers, three levels of AQC are carried out automatically, one level every 4 hours according to a pre programmed timetable. Any sensor failing IQC at one or more levels is disabled by the analyser until the errors are resolved. The AQC cartridges are stored at 2-8<sup>o</sup>C in fridge room 4063 and are stable until expiry date. (Siemens part number 05293926) Cumulative performance for all Analysers is archived by and may be viewed from the RAPIDCOM computer (see separate SOP)

All analysers are registered for monthly EQA under WEQAS

#### **Maintenance procedures –**

- 1. EACH LOCATION REQUIRES A DAILY VISIT AND according to each instruments' schedule weekly maintenance must be carried out. (For low use instruments, 6B, BGH Lab & BGH ward 11 this should be carried out ever two weeks) N.B. It is essential that one of the ITU analysers is always available. Therefore maintenance must always be completed on one analyser before commencing work on the second.
- 2. 405 & 1200 series analysers require their cartridges to be changes at defined intervals.
- 3. The analysers based at LWH HDU and BGH WD 11 are maintained by trained ward staff. For BGH WD 11 this is the ward manager For LWH HDU contact the ward manager
- 4 When laboratory staff visit clinical areas to carry out maintenance or to train staff a clean laboratory coat must be worn. When entering wards or clinical areas hands must be cleaned with the alcohol based hand rub provided. A bottle of this must be carried in event of their being no supply at the entrance to the ward.

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## SIEMENS 1200 SERIES ANALYSERS SOP FOR LABORATORY BASED OPERATORS & WARD STAFF TRAINED IN MAINTENANCE PROCEDURES.

- 1) Analyser Overview
- 2) Maintenance Procedures

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#### OPERATING PROCEDURES FOR SIEMENS 1200 SERIES ANALYSERS

#### 1) Analyser overview

The 1200 series analysers use the same electrode system as the earlier 800 series analysers and the maintenance of these is similar, although the PCO2, PO2, Ca, and reference sensors are specific for the 1200 series and labelled as such. The reagent cartridge, control systems, sample analysis and AQC are similar to the 400 series. They are as follows: -

Automatic QC cartridge 05293926, store at  $2-8^{\circ}$ C in cold room 4063 (this is the same as the 400 series) Reagent cartridge 03909458 store at  $2-8^{\circ}$ C in cold room 4063

Wash Cartridge 03913056 store at room temp. in room 4010

#### Siemens 1200 operation

Communication with the analyser is by the touch sensitive screen or bar code reader. Using this, enter your PIN or Laboratory access code and press the green arrow in the bottom right corner of screen. Patient samples may be assayed by following the instructions on this screen, also shown down the middle of the screen are a list of the sensors in use and their calibration status. In the top RH corner of the screen are three touch activated icons, The LH icon gives access to the archive of patient, calibration and QC data. The middle icon gives access to the analyser status and maintenance screen. Access to the set up function for the analyser is also through this screen (requires high level password for access – this is known by staff who have received advanced training) The 'help' files are accessed through the RH (?) icon

<u>Clot removal</u> – Large clots will be prevented from entering the analyser by the orange sample port. If prompted by the analyser this must be replaced from a stock kept with the analyser (extra supply kept with blood gas spares in the laboratory store-room). Clots that lodge further in the analyser may be removed by flushing with water from a syringe as follows: -

- Eject both reagent and wash cartridges From 'Diagnostics' menu select cartridges, followed by eject both cartridges.
- Remove manifold from behind cartridges by unclipping and disconnecting the analyser tubing, flush all connectors with water from a syringe.
- Holding the reagent cartridge upright (as fitted on analyser) locate the five connector nipples at rear of cartridge and flush the TOP THREE only with water from a syringe.
- Examine the line of sensors and the Co-Ox chamber for obstructions and carefully remove using GENTLE flushing if necessary, this is facilitated by replacing the PO2 sensor with Siemens 'CLOT REMOVER' tool (part no. 10378229) and gently injecting water from a syringe into the sample path. Ensure that a piece of gauze it held at the connector with the manifold to catch the clot. **GLOVES MUST BE WORN.**
- Replace manifold and cartridges, close analyser doors and recalibrate the system.

#### 2) Maintenance procedures

#### **Daily**

- 1. Check Rapidcomm for cartridge status sensor stability and IQC performance
- 2. Check analyser status screen.
- 3 Change analyser cartridges if required instruction video will be activated when the icon representing the expired cartridge is touched. NB once a cartridge has been removed from the analyser, it cannot be refitted for continuing use. Replacement Reagent and QC cartridges are

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stored in the Endocrine cold room. Wash cartridges and waste containers are kept with other blood gas consumables in the reagent store-room, at least one of each must be kept in the BGH lab to be readily available if required by one of the wards.

Note – the analyser will display a visual warning when any cartridge is within 24 hrs. of expiry or when there are less than 10% remains.

- 4 Clean analyser surface, small blood spots can be removed with 0.5% hypochlorite. Report any misuse of analyser to ward manager and to senior BMS (e.g. blood spills used syringes or needles left on analyser)
- 5 Check and replace printer paper roll, instruction video available through user manual icon (stock of paper with other blood gas analyser supplies in reagent store room)
- 6 Service or replace any failed sensors

Note that if any of the sensors have been replaced or disturbed then the analyser must be fully calibrated and all levels of IQC measured before anyone is permitted access to analyse samples.

<u>Used cartridges must be treated as contaminated waste and disposed at the site of use in 'vellow clinical waste bags'</u>

#### Additional periodic maintenance -

Check the maintenance logs for additional maintenance required. This should be undertaken on the daily visit and performed **BEFORE THE DAILY PROCEDURES**.

Complete the maintenance log-sheets for all activities performed.

If glucose or lactate sensors are fitted, analyse the Siemens High G/L control weekly, (Core lab cold room with glucose & lactate sensors), this should be on the last day before the weekend or Bank Holiday break. Replace glucose or lactate sensors if this falls below the lower limit defined for the control and as stated in the log-sheet.

Before performing maintenance procedures on any sensors, log onto the analyser using your access code. Touch the **Status** icon followed by **Maintenance** and **Performing Sensor Maintenance**.

#### To install glucose or lactate sensors –

- Remove a sensor from fridge and LEAVE IN THE SEALED PACKET AT ROOM TEMPERATURE FOR AT LEAST 30 MINUTES TO EQUILIBRATE (this prevents condensation on the electrode which would render it unsuitable for use).
- 2) Open the electrode compartment. Release the clamp on the right, which holds all sensors in place.
- 3) Remove the old sensor and install new, ensure that the sensor is making good contact at all four points.
- 4) Close compartment
- 5) Calibrate the sensor.

N.B. the sensor may require up to 30 minutes before stabilizing and satisfactory calibration. If successful calibration is not achieved after at least one hour and/or several calibration attempts, remove another electrode from the fridge and install this after the 30 minute warm up period as described above.

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#### To install a PO2 or PCO2 sensor –

As for installing glucose sensor except that PO<sub>2</sub> & PCO<sub>2</sub> are stored at room temperature so do not require to be equilibrated to room temperature before use

#### **Weekly Maintenance Procedures**

Check the electrolyte level in each of the sensors, top up or replace as necessary.

#### To install or service an electrolyte sensor (Na, K, Cl, Ca, pH)

These sensors and associated fill solutions are stored at room temperature.

- i) The box containing the sensor also contains a filling needle & a vial of filling solution. This solution is interchangeable between Na, K, Cl, Ca sensors. The pH fill solution is unique to the pH sensor.
- ii) Remove the centre electrode by unscrewing from the body of the sensor and set to one side taking care not to touch the central pin. Fit the filling needle to the vial of electrode fill solution & fill the body of the sensor from the bottom to no more than 80% full for K, Cl & Ca sensors and 90% full for Na & pH sensors. Refit the central electrode & gently tap the sensor to ensure that there are no bubbles on the membrane.
- iii) Open the electrode compartment. Release the clamp on the right.
- iv) Remove the old sensor and install new
- v) The response of the sensor can often be restored by replacing the sensor fill solution.

  To do this, unscrew the centre electrode & set to one side taking care not to touch the central pin. Gently tap the old electrolyte out onto a tissue and replace with fresh as in step 2, refit the central electrode and tap gently to dislodge any bubbles that may be trapped on the membrane. Refit sensor to the instrument and recalibrate

#### 2) Perform deproteinise and conditioning of electrodes.

- i) Reconstitute a vial of deproteiniser(D1b, pepsin powder)with a vial of D1a electrolyte mixture. Fill a 5ml syringe with the deproteiniser solution.
- ii) Press STATUS > MAINTENANCE > DEPROTEINIZING THE SAMPLE PATH

N.B. if there are glucose or lactate sensors fitted you will be prompted to remove the glucose and lactate sensors and install TB4 dummy electrodes and press OK to confirm BEFORE PROCEEDING WITH DEPROTEINISER. FAILURE TO DO THIS WILL CAUSE IRREPARABLE DAMAGE TO THE SENSORS WHICH WILL REQUIRE REPLACEMENT.

- iii) Insert syringe of deproteiniser to sample port and press ANALYSE Remove syringe when prompted. This takes 5 minutes.
- Instrument will then prompt to ask for CONDITION??
   Transfer the contents of one conditioner vial to a 5ml syringe and present to the analyser sample port and press ANALYSE.

Remove syringe when prompted.

This takes 5 minutes.

You will be prompted to remove the dummy electrodes and re-install glucose and lactate sensors and press OK to confirm BEFORE PROCEEDING WITH CALIBRATION.

v) Instrument will then prompt "CALIBRATE??" press YES to calibrate.

The instrument may require 2 or 3 calibrations after a clean/condition before all electrodes re-stabilise.

Note that if any of the sensors have been replaced or disturbed then the analyser must be fully calibrated and all levels of IQC measured before anyone is permitted access to analyse samples.

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#### OPERATING PROCEDURES FOR RAPIDPOINT 405 ANALYSERS

#### **Analyser Overview**

Measurement sensors for pH, PO<sub>2</sub>, PCO<sub>2</sub>, Na, K, Cl, Ca(Ionized) & Glucose are contained within a sealed Measurement Cartridge which also contains the necessary calibration materials. It is designed to perform 750 assays (400 on LWH HDU & BGH Theatre) within a 28 day period and will expire when the first of these number limits is reached. Liquid waste is collected in a sealed Waste Cartridge, which will last for 10 days on the analyser or until the Measure Cartridge is changed.

Quality control is provided by a sealed QC cartridge with a 28 day in use life. Quality control is programmed to be carried out twice daily for each parameter from this cartridge. Any analyte that falls outside pre determined acceptance limits is disabled by the analyser, and can only be reactivated following a successful re-calibration and repeat QC. All 3 levels will be performed following replacement of the measure cartridge Any sensors that have failed to calibrate before the AQC is assayed will not produce any results until valid QC is next done.

There is little intervention that is possible apart from changing cartridges, printer paper and keeping the analyser clean.

#### **Rapidpoint 405 operation**

Communication with the analyser is by the touch sensitive screen or bar-code reader.

Using this enter your PIN or Laboratory access code and press the green arrow in the bottom right corner of screen. Patient samples may be assayed by following the instructions on this screen, also shown down the middle of the screen are a list of the sensors in use and their calibration status. In the top RH corner of the screen are three touch activated icons, the LH icon resembling a book gives access to the user manual including video clips describing various user & maintenance procedures. The middle icon gives access to the archive of patient, calibration and QC data. The RH icon gives access to the analyser status screen, which will show the usable days remaining on each of the cartridges. Access to the set up function for the analyser is also through this screen (requires high level password for access – this is known by staff who have had advanced training from Siemens)

#### **Maintenance procedures RAPIDPOINT 405**

#### **Daily**

- Check analyser status screen, inform senior BMS if any sensors are marked as inactive. Change analyser cartridges if required instruction video will be activated when the icon representing the expired cartridge is touched. NB once a cartridge has been removed from the RAPIDPOINT 405 analyser, it cannot be refitted to the analyser for continuing use. Replacement Measure and QC cartridges are stored in the Endocrine cold room, Waste cartridges are kept with other blood gas consumables in the reagent store-room. Full automatic IQC will be performed by the analyser as soon as it has completed its' initial calibration. If any sensors have failed to calibrate initially but pass subsequent calibrations, they will not generate results until a valid IQC has been performed at the next automatic cycle. Note the analyser will display a visual warning when any cartridge is within 24 hrs. of expiry or when there are less than 30 assays.
- ii) Clean analyser surface, small blood spots can be removed with 0.5% hypochlorite.

  Report any misuse of analyser to ward manager and to senior BMS (e.g. blood spills used syringes or needles left on analyser)
- iii) Check and replace printer paper roll, instruction video available through user manual icon (stock of paper with other blood gas analyser supplies in reagent store room)

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### <u>Used cartridges must be treated as contaminated waste and disposed at the site of use in</u> 'yellow clinical waste bags'

Conditioning of the measure cartridge with blood or plasma is necessary for optimal performance. If the instrument is frequently used, normal analysis of patient samples will be sufficient for this. If the analyser is only used infrequently then a conditioning sample must be analysed as soon as the

analyser has completed its' initial calibration following installation.

This sample is provided by the laboratory to the appropriate units, the most suitable material being

The sample is transferred to a 1ml syringe and analysed 5 times. The patient data entered should be: - Patient ID - 7654321Q. Last Name BLOGGS. The results obtained have no meaning and should be discarded.

There are two analysers that this should be performed on : - BGH Theatre and LWH HDU

an expired serum IQC.

Failure to carry out this procedure may result in the failure of the Measure Cartridge, which Siemens will then refuse to replace.

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#### TO PERFORM A SAMPLE ANALYSIS ON THE LABORATORY BASED SIEMENS 1200 SERIES ANALYSERS

Specimen requirements – Blood freshly drawn into a heparinised syringe, all air expelled prior to capping and mixing by rotation between the palms of the hands to disperse heparin. Samples for Blood Gas analysis must be packed with crushed ice & water for transport to the laboratory. The sample must be accompanied by a fully completed laboratory request form and the sample must be labelled with the patient demographics. Transport to the laboratory must not be via the pneumatic tube system, any that do arrive by this mechanism must be reported as unsuitable for analysis.

Only syringes supplied for taking of 'Blood Gas Analysis' <u>MUST be used</u>. Use of heparin other than that used in these syringes may give erroneous results and/or damage the analyser.

Other body fluids may be analysed e.g. Pleural fluids for pH, however they must be centrifuged prior to analysis to remove all particulate matter and potential clots,

<u>Analysis procedure</u> — The sample should be booked into Telepath prior to analysis if duplicate sample records are to be avoided.

- 1. Mix the sample by rotating between the palms of the hands for 30 seconds immediately prior to analysis.
- 2. Check that the analyser is in the ready mode (visible top LH corner of screen). If it is calibrating or purging, wait until complete \*DO NOT CANCEL\*. Enter your password/PIN Locate the sample on the Luer fitting and press the GREEN arrow in the bottom RHS of screen. Wait until prompted by the analyser before removing sample. The data entry screen will be displayed and must be completed according to the following protocol:-

by the analyser before removing sample. The data entry screen will be displayed and must be completed according to the following protocol:-
PATIENT ID
Full unit number – As entered into Telepath, this is best entered using the bar-code reader. If an RQ6 number the analyser will retrieve the patient's information from the server (this may be entered before analysis, option 1 on analyser using the bar-code reader)
ACCESSION NUMBER
Laboratory number - As on the Bar-code label, the 'CARD ONLY' bar code may be used to input this.
LOCATION  Requesting unit or ward
TEMPERATURE
If the patients' temperature is entered the analyser will produce temperature corrected pH, pCO <sub>2</sub> , & PO <sub>2</sub> . In no temperature is entered the default is 36.4
FiO2
Enter the patients' inspired oxygen. As percent (if known) N.B. – On air = $21$
OPERATOR ►
THIS WILL CONTAIN YOUR NAME or UNIQUE ID NUMBER, AND IS DEPENDENT ON YOUR PASSWORD. IT CANNOT BE ALTERED.!!

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Please note data fields marked with ▶ are mandatory, and must be completed.

- 3. When all patient data is entered, press the GREEN arrow. The results will print out to include: patient data & the user ID number of the analyst.
- 4. The analyser is interfaced with Telepath via Siemens Rapidcom. If the sample has been registered with telepath the results will download directly. Ensure that results have transferred to T'Path

#### To perform off line analyses on the laboratory based analyser

These will include any direct 'ISE' checks, blood gas samples awaiting identification, and any assays that have not been entered into Telepath for whatever reason.

- 1. Perform the assay as described above but with the data entry fields to be completed as follows: -
- 2. Select panel required from screen.

PATIENT ID	
►OFFLINE	
LAST NAME	
►TEST	
ACCESSION NUMBER	
► Specimen accession numb	oer
This may be entered by read	ing the sample bar-code, this will include the hidden sample type letter.
OPERATOR	
<b>▶</b> 950	

3. Press the GREEN arrow The results will be recorded in RAPIDCOMM
To include operator ID and record of sample analysed in the ACCESSION NUMBER data field

#### To perform analysis using capillary blood gas samples

In the rare event when a paediatric patient has been received in AE and is too ill to transfer to Alder Hey, AE have a supply of capillary sampling devices.

A full capillary sampling device is sufficient for full analysis including co-ox.

- 1. If more than one has been received examine samples visually for obvious clots or air bubbles, discarding these.
- 2. Using a magnet, draw the flea up and down the capillary several times to mix the sample, leaving it at one end of the capillary, remove end cap then the flea using the magnet to draw it out of the capillary.
- 3. Log onto the analyser, remove the other end cap and offer that end of the capillary onto the sample dome. Holding the capillary as close as possible to the sample dome, carefully push the capillary home until it locks into place.
- 4. Press analyse and continue as if analysing an off line analysis (described above)
- 5. Check the validity of results particular note being taken of the presence of bubbles or clots (repeat analysis if necessary and another sample is available).

  Directly enter results into T'Path.

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## SIEMENS RAPIDPOINT 405 AND 1200 SERIES BLOOD GAS & ELECTROLYTE ANALYSERS.

STANDARD OPERATING PROCEDURES FOR WARD BASED OPERATORS

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## BLOOD GAS ANALYSER S.O.P. FOR WARD BASED OPERATORS. SIEMENS RAPIDPOINT 405 & 1200 SERIES

The full SOP for the use of Siemens Blood Gas Analysers, of which the following page is an extract, is located by the Analyser & is also part of the Lab Handbook which may be viewed electronically.

It may also be viewed at: - www.rlbuht.nhs.uk/jps/gas\_sop.pdf (from any P.C.)

The full SOP includes - Principles of analysis, Risk Assessments, instructions for routine maintenance

• LABORATORY SUPPORT – The Blood Science Department will provide a daily service visit to each analyser between 0900h and 1700h Monday to Friday (At the Liverpool Womens support will be provided by the 'Key Trainer', contact details below and at BGH WD 11 by the ward manager) Service visit to include routine maintenance and replenishment of consumables. The Siemens Rapidpoint 400 and 1200 series analysers perform programmed automatic Quality Control analysis at three levels and will disable any parameter that exceeds defined limits. Additional visits outside these hours or in case of breakdown will only be made according to availability of Laboratory staff.

Contact phone numbers are:- 4163 or 4235(out of hours)

GENERAL REQUIREMENTS – It is the responsibility of the ward manager to ensure that the area around the analysers is kept tidy and any spillage of sample is cleaned up promptly.
 The Laboratory reserves the right to withhold support where there is misuse of an analyser.
 The touch sensitive screen must be operated with fingers only, use of pens or sharp objects will cause serious damage to the analyser.

- <u>DECONTAMINATION</u> Spillage of blood or other body fluids should be cleaned using a lint free cloth and 0.5% Sodium Hypochlorite solution (Dilute Bleach) **Alcohol wipes must not be used.**
- SPECIMEN REQUIREMENTS Blood freshly draw into a Siemens Rapidlyte blood gas syringe, all air expelled prior to capping and mixing by rotation between the palms of the hands to disperse heparin. Samples for Blood Gas analysis must be packed with crushed ice if there is any delay (>10minutes) between drawing of sample and analysis.
   The sample must be re-mixed immediately before analysis.
   NB a minimum of 1ml blood is required for analysis on the 405 analysers, 0.5 ml for the 1200.
   Only syringes supplied for taking of 'Blood Gas Analysis' MUST be used. Use of heparin other than that used in these syringes may give erroneous results.

If it is required to analyse samples other than whole blood they must be sent to the Blood Science Lab.

- <u>STAFF TRAINING</u> All users of ward-based, Blood Gas Analysers must be trained by the Blood Science Laboratory prior to being issued with a password/personal identification number. It is impossible to use the analysers without a valid password/PIN.
- <u>To arrange for training</u>, Tel. 4163 or email <u>David.Harrison@rlbuht.nhs.uk</u> <u>Kath.ashton@rlbuht.nhs.uk</u> or <u>Lesley.Allars@rlbuht.nhs.uk</u> At Liverpool Womens Hospital contact the ward manager of GYN HDU

#### Access to the Blood Gas Analysers -

Access to any of the blood gas analysers is by password/PIN. The Blood Science Department will issue this following training. Access to the analysers will be disabled under the following circumstances: -

- If the manager of the unit owning the analyser requests that an individual is to be removed.
- When a member of staff leaves the employment of the trust.
- When an individual's access code has become compromised or is suspected to be compromised.
- In event of serious misuse of an analyser.
- Repeated failure to follow the 'Standard Operating Procedure' for the use of an analyser.
- Failure to attend periodic training updates.

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The full SOP for the use of Siemens Blood Gas Analysers, of which the following page is an extract, is located by the Analyser & is also part of the Lab Handbook which may be viewed electronically.

It may also be viewed at: - www.rlbuht.nhs.uk/jps/gas sop.pdf (from any P.C.)

To perform a Blood Gas Analysis the operator must have been present when the sample was drawn.

• Performing blood gas analysis (Siemens Rapidpoint 405 & 1200 series analysers)

Check that the analyser is 'READY' (visible in top LH corner of screen).

A yellow triangle with legend 'ANALYSER REQUIRES OPERATOR ATTENTION' is for laboratory information and may not indicate an immediate problem with the analyser

The analyser is operated using a touch sensitive VDU and the connected Bar-Code-Reader, it is also possible to access a full training manual including video clips for the most commonly performed operations. Using this screen, enter your PIN & press the green arrow in the bottom right corner, if your password is on a bar-code, scan it with the reader. Locate the sample in the Luer fitting & press the green arrow. Remove the sample when prompted and press the green arrow.

If the 1200 analyser detects a short sample it will offer the option of 'micro sample' Follow the on screen instructions if this is required. The data entry screen will now be available and the data fields must be completed according to the following protocol: -

	FULL UNIT NUMBER as shown in examples below
	RQ61234567, 5NL0001234, W0123456 or NHS number is acceptable. If the unit number has an
	associated bar-code it should be scanned with the reader. For RQ6 numbers, the analyser will
	interrogate the Hospital database, if the record is found the following LAST NAME data-field will be
	completed (note that data retrieved cannot be altered on the analyser). If it is not found then the LAST
	NAME data-field must be completed as follows: -
	•
	LAST NAME
	<b>&gt;</b>
	PATIENT'S FAMILY NAME
	When patient's ID is not known the above fields should be filled with as much information as possible,
	otherwise enter 'UNKNOWN' + 'time of admission' in the 'PATIENT ID' field,
	and 'patient sex' + time of admission in 'LAST NAME' field
	LOCATION
R	REQUESTING UNIT OR WARD
1	EMPERATURE
I	f the patient's temperature is entered the analyser will produce corrected results, if no entry 36.4 is the default.
	r

FiO2

**>** 

ENTER THE PATIENTS INSPIRED OXYGEN (On air = 21)

This will then be printed on the report to aid interpretation of results.

**USER ID** 

**PATIENT ID** 

**>** 

THIS WILL CONTAIN YOUR UNIQUE ID NUMBER, IT IS DEPENDENT ON YOUR PASSWORD.

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#### **APPENDICES**

Appendix A – Blood Gas & Acid base

**Appendix B** – Co-oximetry

**Appendix C** – Blood Electrolytes

**Appendix D** – Metabolites (glucose & lactate)

<u>Appendix E</u> – Health & safety (Risk assessments)

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#### **APPENDIX A**

#### Blood Gas - Acid Base

#### <u>pH</u>

Extra-cellular pH correlates closely with intracellular pH. pH is therefore valuable as a general indicator of intracellular acid-base status. pH is clinically significant as a means of determining acid-base disorders that can be caused by several pathological conditions such as ventilatory dysfunction and renal or gastrointestinal inadequacy.

#### **Principle of analysis**

The pH sensor is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. The pH sensor contains a Silver/Silver Chloride wire surrounded by a buffer solution.

A glass membrane that is highly sensitive and specific for  $H^+$  ions separates the sample from the buffer solution.

When sample comes into contact with the glass membrane the passage of  $H^+$  ions generates a potential, which is measured by a voltmeter. This reflects the  $H^+$  concentration (& therefore pH) when compared to the constant potential generated by the reference electrode  $pH = log 10[H^+]$ 

#### Reference Range -

pH 7.34 - 7.44 H<sup>+</sup> ion 36 - 42 nmol/l

#### Reporting range - pH

6.50 – 7.80 (400 series analysers) 6.00 – 8.00 (800 & 1200 series analysers)

**Interferences** – None reported

#### $pCO_2$

Carbon dioxide is a product of cell metabolism and is transported via the blood as carbonic acid and bicarbonate to the kidneys and lungs for excretion.

The lungs are primarily responsible for controlling the pCO<sub>2</sub> levels through the excretion of CO<sub>2</sub>, changes in pCO<sub>2</sub> reflect respiratory status. pH and pCO<sub>2</sub> measurements together provide a more definitive diagnostic tool in assessing respiratory dysfunction and acid-base disorders.

#### **Principle of analysis**

The pCO<sub>2</sub> sensor is a complete electrochemical cell that consists of a measuring electrode and an internal reference electrode. The measuring electrode, which is a pH electrode is surrounded by a Chloride/Bicarbonate solution. A membrane, permeable to gaseous CO<sub>2</sub> separates this solution from the sample. The internal reference electrode, which contains a Silver/Silver Chloride electrode surrounded by the Chloride-Bicarbonate solution, provides a fixed potential.

**Reference Range** – (Arterial)

4.7-6.0 kPa

#### Reporting range $-pCO_2$

1.33 – 20.00 kPa (400 series analysers) 0.67 – 33.33 kPa (800 & 1200 series analysers)

**Interferences** – None reported

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#### $\mathbf{pO}_2$

Oxygen (O<sub>2</sub>) is essential for cell and tissue metabolism. Oxygen transport comprises four major steps: -

- Convection and diffusion from the air into the pulmonary circulation.
- Combination of O<sub>2</sub> with haemoglobin within the red cells to form oxy-haemoglobin.
- Transportation via the arteries to the cells.
- Release into the tissues and utilisation of  $O_2$  at the cellular level.

The measurement of arterial  $pO_2$  is used to indicate the arterial tension within arterial blood and therefore the degree of hypoxaemia present in a patient sample.

#### Principle of analysis

The  $pO_2$  sensor is a complete electrochemical cell that incorporates amperometric technology. The sensor consists of a platinum cathode and a silver anode, an electrolyte solution and a gas permeable membrane.

A constant (polarizing) voltage is maintained between the anode and the cathode. As dissolved oxygen passes through the membrane into the electrolyte solution it is reduced at the cathode.

$$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$$

The circuit is completed at the anode when the silver is oxidized.

$$4Ag \rightarrow 4Ag^+ + 4e^-$$

The amount of reduced oxygen is directly proportional to the number of electrons gained at the cathode.

#### **Reference Range** – (Arterial)

11.3 - 14.0 kPa

#### Reporting range $-pO_2$

1.33 – 93.32 kPa (400 series analysers) 0.00 – 106.67 kPa (800 & 1200 series analysers)

<u>Interferences</u> – None reported

#### Standard bicarbonate.

The bicarbonate ion (HCO<sub>3</sub><sup>-</sup>) is the major buffer substance in the body, and plays a major role in maintaining blood pH.

It is calculated as follows –

$$(HCO_3^-) = 24.5 + 0.9A + (A - 2.9)^2 (2.65 + 0.31 \text{ Hb})/1000$$

where

$$A = BE(B) - 0.2(Hb) (100 - O_2SAT)/100$$

The Hb may be an assayed value from the associated co-oximeter, derived from a measured haematocrit or it can be an assumed value entered into the analyser set-up.

**Reference Range** 22 – 26mmol/l

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#### **Base excess**

The calculation of the base excess of blood permits the estimation of the number of equivalents of sodium bicarbonate or ammonium chloride required to correct the blood pH to 7.40

The base excess, in blood, with a pH of 7.40, - pCO $_2$  of 5.33 kPa - Hb of 15.0 g/dl at  $37^{o}C$  is zero.

It is calculated as follows –

$$BE(B) = (1 - 0.014 * Hb) [(HCO_3^- - 24.8) + (1.43 * Hb + 7.7)(pH - 7.40)]$$

The Hb may be an assayed value from the associated co-oximeter, derived from a measured haematocrit or it can be an assumed value entered into the analyser set-up.

 $HCO_3^-$  (actual) is derived as follows: -  $log HCO_3^- = pH + log(pCO_2 * 0.0307) - 6.105$  (National Committee for Clinical Laboratory Standards Recommendations)

#### **Reference Range –**

 $-2.3 - \pm 2.3 \text{mmol/l}$ 

#### **Turnaround time**

Samples analysed immediately upon receipt.

#### **Assay characteristics**

Precision: -	pН	=	0.08%	pН	7.1 - 7.6
	$pC0_2$	=	2.3	$pC0_2$	2.0 - 19.0
	$p0_2$	=	4.1	$p0_2$	4.0 - 93.0

#### **Reference Range**

pН	7.34 - 7.44
$pCO_2$	4.7 - 6.0
$p0_2$	11.3 - 14.0
Std Bicarbonate	22 - 26
Base Excess.	-2.3 - +2.3

#### **Further Information**

Maintenance and reagent logs must be completed daily.

Specimens arriving with needle still attached <u>must not</u> be analysed. The medic who took the sample should be requested to either come to the laboratory and remove the needle <u>or</u> send an alternative specimen. Calibration is automatic and occurs at pre programmed intervals.

#### **References**

- 1. Hamilton, L.H. Respiratory and blood gas analysis. Prog Clin Pathol 1969; 9: 284-340.
- 2. Van Slyke, D.D. Cullen, G.E. Studies of acidosis J. Biol Chem

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#### **APPENDIX B**

#### **CO-oximetry**

This module, if present, measures Haemoglobin and other related compounds in whole blood at the same time as blood gas analysis.

#### **Principle of analysis**

The CO-oximeter measures haemoglobin and related compounds by passing polychromatic light through a lysed sample of blood. The reflected light is measured at several wavelengths so differentiating between the compounds according to their absorbance spectra.

#### Interferences -

CO-oximetry is affected by the presence of turbidity, bilirubin, cyanmethaemoglobin and dyes in the sample.

#### Haemoglobin -

Haemoglobin is a tetrameric protein consisting of two pairs of polypeptide chains, each chain having a haem group containing one atom of Iron. Each molecule of Haemoglobin can bind up to four molecules of oxygen, one at each haem group. Haemoglobin has a key role in the transport of oxygen from the lungs to the tissues. Haemoglobins' ability to bind & release oxygen depends on several factors: - pH, PCO<sub>2</sub>, PO<sub>2</sub>, diphosphoglycerate concentration & temperature.

The presence of dyshaemoglobins such as carboxyhaemoglobin, methaemoglobin, sulfhaemoglobin may also affect normal oxygen transport mechanism. Abnormal concentrations of haemoglobin variants such as foetal haemoglobin may also affect this.

The measure of total haemoglobin includes all these fractions of haemoglobin plus the oxygenated and reduced forms.

**Reference Range** – 12.0 – 18.0 g/dL

#### Oxyhaemoglobin (O<sub>2</sub> Hb) –

This is the fraction of haemoglobin that is reversibly bound to oxygen

**Reference Range** – 94.0 – 97.0% (Arterial)

#### **Deoxyhaemoglobin** – (HHb)

Refers to the haemoglobin capable of binding oxygen (sometimes referred to as reduced haemoglobin)

**Reference Range** – 0.0 – 5.0% (Arterial)

#### **Methaemoglobin** – (MetHb)

Methaemoglobin is haemoglobin whose iron has been oxidized to Fe<sup>3+</sup> and is unable to bind oxygen.

**Reference range** -0.0 - 1.5% (Arterial & Venous)

#### Carboxyhaemoglobin – (COHb)

Carboxyhaemoglobin is haemoglobin covalently bound to carbon monoxide.

**Reference range** – 0.1-0.4% (venous or arterial, non smokers)

Air pollution and smoking may result in significantly higher levels than this.

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#### **APPENDIX C**

#### **ELECTROLYTE ASSAYS**

#### **Sodium**

#### Principle of analysis

The sodium sensor is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. The Na sensor contains a Silver/Silver Chloride wire surrounded by an electrolyte solution with a fixed concentration of Na & Cl ions

A glass membrane that is highly selective for sodium ions over other clinically encountered cations, separates the sample from the electrolyte solution.

When sample comes into contact with the glass membrane the exchange of Na<sup>+</sup> ions generates a potential, which is measured by a voltmeter. This reflects the Na<sup>+</sup> concentration when compared to the constant potential generated by the reference electrode.

As the sample is not pre-diluted as with the routine laboratory analysers, this assay (direct ISE) is not subject to pseudo dilution effect and therefore is the method of choice when paraproteinaemia or hypertriglyceridaemia is suspected.

#### Reference range -

135 – 145 mmol/l (Plasma)

Whole blood slightly lower (Reference range – not established)

**Reporting range**: 100 - 200 mmol/l (400 series analysers)

70 - 200 mmol/l (800 & 1200 series analysers)

<u>Interfering substances</u> – The following substances were found to interfere with the Sodium assay: -

Substance	Concentration tested	Level of interference
Dobutamine	5mg/dl	+6.0 mmol/l
Benzalkonium Heparin		> 50 mM
Heparine Leo	800 – 850 U/ml	-12.6 mM

It is recommended that the sample be treated as 'mixed venous' when Benzalkonium Heparin is used. Some pulmonary artery catheters may also contain the Benzalkonium ion, which interferes with analysis.

#### **Potassium**

#### **Principle of analysis**

The potassium sensor is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. The 'K' sensor contains a Silver/Silver Chloride wire surrounded by an electrolyte solution with a fixed concentration of potassium ions

Ionophore valinomycin immobilised in a plasticised PVC matrix forms the membrane that separates the sample from the electrolyte solution. Valinomycin is a neutral ion carrier that is highly selective for potassium ions over other clinically encountered cations.

When sample comes into contact with the valinomycin membrane the exchange of  $K^+$  ions generates a potential, which is measured by a voltmeter. This reflects the  $K^+$  concentration when compared to the constant potential generated by the reference electrode

#### Reference range -

3.5 - 5.0 mmol/l (Plasma)

Whole blood slightly lower (Reference range – not established)

**Reporting range:** 0.50 - 15.0 mmol/l (400 series analysers)

0.50 - 9.99 mmol/l (800 & 1200 series analysers)

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#### Interferences -

Benzalkonium Heparin has been shown to interfere with potassium sensor, increasing apparent levels by >0.15 mmol. It is recommended that the sample be treated as 'mixed venous' when Benzalkonium Heparin is used. Some pulmonary artery catheters may also contain the Benzalkonium ion, which interferes with analysis.

Caution should be exercised when interpreting whole-blood potassium assays as haemolysis, which may falsely elevate the potassium level, will not be apparent.

#### **Chloride**

#### Principle of analysis

The chloride sensor is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. The chloride sensor contains a Silver/Silver Chloride wire surrounded by an electrolyte solution with a fixed concentration of chloride ions

A derivitized quarternary ammonium compound immobilised in a polymer matrix, forms the membrane that separates the sample from the electrolyte solution. The membrane acts as an ion exchanger that is highly selective for chloride ions over other ions in the sample.

When sample comes into contact with the membrane the exchange of Cl<sup>-</sup> ions generates a potential, which is measured by a voltmeter. This reflects the Cl<sup>-</sup> concentration when compared to the constant potential generated by the reference electrode

**Reference range** 99 - 109 mmol/l (Plasma)

Whole blood slightly lower (Reference range – not established)

**Reporting range:** 65 - 140 mmol/l (400 series analysers)

40 – 160 mmol/l (800 & 1200 series analysers)

**Interfering substances** – The following substances were found to interfere with the Chloride assay: -

Substance	Concentration tested	Level of interference
Salicylic acid	50mg/dl	+9.5 mmol/l
Salicylic acid	20mg/dl	+1.8 mmol/l

#### **Ionised Calcium**

#### **Principle of analysis**

The calcium sensor is a half-cell that forms a complete electrochemical cell when combined with the external reference sensor. The 'Ca' sensor contains a Silver/Silver Chloride wire surrounded by an electrolyte solution with a fixed concentration of calcium ions

An Ionophore immobilised in a PVC matrix forms the membrane that separates the sample from the electrolyte solution. The ionophore is a compound that is highly selective for calcium ions over other ions. When sample comes into contact with the membrane the exchange of Ca<sup>++</sup> ions generates a potential, which is measured by a voltmeter. This reflects the Ca<sup>++</sup> concentration when compared to the constant potential generated by the reference electrode

**Reference range** -1.15 - 1.30 mmol/l (Plasma at pH 7.4)

Whole blood slightly lower (Reference range – not established)

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**Reporting range**: 0.20 – 5.00 mmol/l (400 series analysers)

0.25 - 5.00 mmol/l (800 & 1200 series analysers)

<u>Interfering substances</u> – The following substances were found to interfere with the Calcium assay: -

Substance	Concentration tested	Level of interference
Salicylic acid	50mg/dl	-6%
Salicylic acid	30mg/dl	-3%

#### **APPENDIX D**

#### **METABOLITES**

#### Principle of analysis

The glucose & lactate sensors are complete electrochemical cells that incorporate amperometric technology to measure glucose or lactate concentration in samples. The sensors consist of 4 electrodes

The measuring electrode contains platinum and either glucose oxidase or lactate oxidase in a binder, while the reference electrode is silver/silver chloride. Of the remaining two electrodes one is a platinum conductor that ensures a constant applied potential, the 4<sup>th</sup> electrode is another measuring electrode without the enzyme. This determines interfering substances in the sample, subtracting them from the total measurement. A microporous cover membrane separates the electrodes from the sample.

A constant polarizing voltage is maintained during analysis.

The relevant reactions are shown below: -

#### Glucose

Glucose oxidase acts on glucose in the sample to form hydrogen peroxide and gluconic acid.

$$C_6H_{12}O_6 + H_2O \longrightarrow C_6H_{12}O_7 + H_2O_2$$
 Where GOX is the glucose oxidase

The polarizing voltage causes oxidation of the hydrogen peroxide

$$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$$

The loss of the electrons creates a current flow that is directly proportional to the level of glucose in the sample.

#### **Lactate**

Lactate oxidase acts on lactate in the sample to form hydrogen peroxide and pyruvic acid.

$$C_3H_6O_3+H_2O+O_2 \longrightarrow C_3H_4O_3+H_2O_2$$
 Where LOD is the Lactate oxidase

The polarizing voltage causes oxidation of the hydrogen peroxide

$$H_2O_2 \rightarrow 2H^+ + O_2 + 2e^-$$

The loss of the electrons creates a current flow that is directly proportional to the level of lactate in the sample.

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<u>Interfering substances</u> – The following substances were found to interfere with the glucose assay: -

Substance	Concentration tested	Level of interference
Sodium Fluoride	1000mg/dl	+1.4 mmol/l
Acetoaminophen	2mg/dl	+0.4 mmol/l
Sodium Fluoride/	1000mg/dl	+1.4mmol/l
potassium oxalate	(each)	
Pralidoxime	16ug/l	
Iodide		

#### Lactate

<u>Interfering substances</u> – The following substances were found to interfere with the lactate assay: -

Substance	Concentration tested	Level of interference
Sodium Fluoride	1000mg/dl	+1.0 mmol/l
Acetoaminophen	2mg/dl	+0.35 mmol/l
Sodium Fluoride/	1000mg/dl	+1.0 mmol/l
potassium oxalate	(each)	
Pralidoxime	64/ug/l	
Iodide		

There have also been reports of positive interference to the Lactate assay from Ethylene Glycol and its' following metabolites: - Glycolic Acid, Formic Acid, Oxalic Acid and Glyoxylic Acid. At time of SOP revision these had not been quantified

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#### **APPENDIX 'E'**

RISK ASSESMENTS